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PATENT  
Customer No. 22,852  
Attorney Docket No. 2405.0167

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:	)	
	)	
Mads Liendgaard Vigh et al.	)	Group Art Unit: 1623
	)	
Application No.: 09/255,655	)	Examiner: H. Owens, Jr.
	)	
Filed: February 23, 1999	)	
	)	
For: USE OF D-TAGATOSE AS A	)	Confirmation No.: 8849
PREBIOTIC FOOD COMPONENT	)	

**Mail Stop Appeal Brief--Patents**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**REPLY BRIEF**

This reply brief is filed under 37 C.F.R. § 41.41(a) in reply to the Examiner's Answer mailed November 8, 2004. Since January 8, 2005, was a Saturday, this Reply Brief filed January 10, 2005 is timely.

On page 2 of the Examiner's Answer, it is alleged that the Appeal Brief filed May 17, 2004, does not contain a statement regarding related appeals and interferences. The statement "NONE" at the top of page 2 of the Appeal Brief is considered to comply with the requirements of 37 C.F.R. § 41.41(c)(1)(ii).

On page 3 of the Examiner's Answer, it is stated that "Zehner anticipates the claims cited supra as it teaches (columns 2-4, claims 1-3) the oral administration of D-tagatose to a human in a dose of 1 g/kg body weight, which encompasses the

claimed daily administration of 5 to 30 grams.” Each of the independent claims under rejection is only 4 lines long, yet the Examiner relies on 3 columns of text and 3 claims of Zehner in an attempt to show anticipation. This lack of precision is only one indication of the flaws in the position of the Examiner. As noted in the Appeal Brief, there is NO disclosure in Zehner that would associate a dose of 1 g/kg body weight (described ONLY in claim 2 of Zehner) with a daily dose. The suggestion by the Examiner that the dosage taught in Zehner “encompasses” the claimed daily dose is not accurate and is without any basis in the Zehner patent.

At the top of page 6 of the Examiner’s Answer, appellants’ dosage argument is acknowledged, but countered (not with a denial or even an alternative interpretation) with the following plainly erroneous statement:

However, Zehner actually teaches the dose in example 1 of the disclosure, moreover, the dose is administered within a 24 hr. period which constitutes a daily dose.

First, Example 1 of Zehner relates to the treatment of 8-week old rats, not humans. Second, there is no disclosure in Example 1 of Zehner of treatment over any particular period of time, and most certainly no reference to a 24 hour period or any other reference to a daily dose. Accordingly, the Examiner has not and can not establish any teaching in Zehner related to a daily dose for any mammal, particularly a human.

In the second full paragraph on page 6 of the Examiner’s Answer, it is stated that “the prior art does not need to indicate whether it is applicable for an adult or child when there is a dosage present in the prior art for one of skill in the art to base administration on.” This was in response to the argument in the Appeal Brief that inherency must be

based on what necessarily occurs according to the teachings in the prior art, not on what is possible or even probable or even what might be selected by a person skilled in the art under specific circumstances that are not described in Zehner. Zehner does not describe administering D-tagatose to a human having the needs described in either claim 13 or claim 18 who weights less than about 81 pounds. As noted in the Appeal Brief, this would be a necessary (but not a sufficient) condition for it to be even possible for Zehner's 1 gram/kg body weight teaching to fall within the scope of the present claims. To support a position of anticipation, it is necessary for the USPTO to establish that each limitation is necessarily taught by Zehner, not that it may be possible for the limitations to be satisfied if certain conditions are met. Unless all the conditions necessary to meet the limitations of the claim are satisfied and described, either explicitly or inherently, it is not possible for Zehner to anticipate any of the claims on appeal.

Finally, in the paragraph bridging pages 6 and 7 of the Examiner's Answer, it is argued that Zehner is not limited to diabetic populations, but also teaches the reduction of the formation of advanced glycosylated end products which may form from hyperglycemia, which is alleged to be a benefit that may be conferred to both diabetic and non-diabetic subjects. While this may be true, the only disclosure in Zehner relating to a dosage for mammals is in the treatment of diabetes (claim 2 of Zehner which is dependent on claim 1). There is no disclosure in Zehner for any suitable dosage for humans, daily or otherwise, for any condition other than diabetes. Accordingly, the only relevant disclosure of Zehner for anticipation purposes must be limited to the treatment of diabetes.

Appellants are aware of the principles of inherent anticipation that the Examiner has relied on, citing Ex parte Novitzki, 26 USPQ2d 1389 (Bd. Pat. App. & Intf. 1993) and other cases. These principles are not applicable to the facts in this case because it has not been shown that the claimed process itself is old requiring administration of D-tagatose to a human having recited specific needs in a recited daily amount of 5 to 30 grams. The Examiner has not and cannot show that these limitations recited in each of the claims on appeal necessarily flow from the teachings of Zehner. See Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Intf. 1990).

For all the reasons set forth in the Appeal Brief and the Reply Brief, the rejection of claims 13-22 under 35 U.S.C. § 102(b) over Zehner et al. (U.S. Patent No. 5,447,917) is fatally flawed and should be reversed.

Please grant any extensions of time required to enter this Appeal Brief and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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GARRETT & DUNNER, L.L.P.

Dated: January 10, 2005

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